K132901

JUN 09 2014

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date Sent	May 14th, 2014
Company Name/ Owner	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia
Submitter Name	Mr. Jean-Nicolas Boudaud Regulatory Affairs Manager, Patient Interface +61 2 88841000 (phone) +61 2 88842004 (fax) Jean.boudaud@resmed.com.au
Correspondent Details/ Official Contact	Mr. Jim Cassi Vice President - Quality Assurance Americas 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: (858) 836 6081
Trade/Device Name	AirSoft F15
Device Common Name	Vented Full Face Mask
Regulation Number	21 CFR 868.5905
Regulation Name	Noncontinuous Ventilator (IPPB)
Regulatory Class	Class 2
Product Code	BZD
Predicate Devices	Quattro Air (K123979) Ultra Mirage FFM (K023244)
Description	The **AirSoft F15** Mask system is an externally placed mask covering the mouth and the nose of the patient. It provides a seal such that positive pressure from a positive pressure source is directed to the patient's nose and/or mouth. It is held in place with an adjustable headgear that straps the mask to the face. **AirSoft F15** can be cleaned by the patient in the home environment and reprocessed by professionals in the hospital/institutional environment. **AirSoft F15** is intended to be used under the conditions and purposes indicated in the labelling provided with the product. **AirSoft F15** is a prescription device supplied non-sterile.

Intended Use

The **AirSoft F15** is a noninvasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as continuous positive airway pressure (CPAP) or bilevel system.

The **AirSoft F15** is:

- to be used by patients (weighing >66 lb (30 kg)) for whom positive airway pressure therapy has been prescribed
- intended for single-patient reuse in the home environment and multipatient reuse in the hospital/institutional environment.

Intended Use comparison

Comparison with predicate Quattro Air (K123979)

The new device and the predicate Quattro Air mask have identical intended uses. Both are intended to be used with Positive Air Pressure therapy equipment, in the same environments for use and for an identical patient population.

Technological Characteristics comparison

Comparison with the predicate Quattro Air (K123979)

AirSoft F15 broadly reuses the technological characteristics and design features of the previously cleared ResMed Quattro Air Full Face Mask

- Both devices have very similar physical properties and operating principle
- Both masks are offered in various sizes and are provided with very similar adjustable headgears. They aim to fit the same patient population
- Both masks incorporate diffuse type vent holes to provide continuous air leak to flush out and minimize the amount of CO_2 re-breathed by the patient. The design of the mask components is such that the incorporation of these vent-holes does not interfere with the intended performance of the mask
- Both masks are equipped with a common elbow component, which can freely rotate through 360 degrees and includes an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded
- Both masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1:2004). The swivel connector can also rotate freely through 360 degrees

The main differences between the predicate Quattro Air (K123979) and the new AirSoft F15 mask system are:

- the sealing interface – the predicate device utilizes a conventional silicone cushion interface whereas the new AirSoft F15 mask system utilizes an alternate conforming material
- the design of certain components (e.g. frame) and how components interface with each other (e.g. retention features,

location and shape of these interfaces)

In addition, the AirSoft F15 Mask system was developed within a risk management process in accordance to ISO 14971:2007, Medical devices - Application of risk management to medical devices. Both devices are designed and manufactured under the same 21 CFR 820 compliant Quality system.

Performance Data

Comparison with the predicate Quattro Air (K123979)
Performance data is provided to demonstrate that the AirSoft F15 design choices do not impact the fundamental scientific concept nor the therapeutic effects of the new device when compared to the predicate.

Both the new mask and the predicate device are designed to operate on the same *Full Face Mask* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both devices are identical in the labelled performance range for each device.

Comparison with the predicate Ultra Mirage FFM (K023244)
CO_2 washout performance testing of the AirSoft F15 demonstrates that it is substantially equivalent to the predicate Ultra Mirage FFM (K023244).

Non-Clinical test data

Extensive testing was performed pre and post cleaning or disinfection of the AirSoft F15 mask to demonstrate that the new device is substantially equivalent to the predicate Quattro Air (K123979) when used in accordance with the supplied instructions for use.

Pressure-flow characteristics and through impedance of the new mask were tested for comparison to the predicate devices and the relevant published data to ensure clinicians are able to prescribe the appropriate therapy when using the new device.

The CO_2 performance (physical and functional dead space) of the new device was also tested and demonstrated substantially equivalent to the predicates. This ensures the new mask design provides adequate venting to flush out the expired CO_2.

As was the case with the predicates, the AirSoft F15 materials not previously cleared by FDA were subject to appropriate biocompatibility evaluations according to ISO 10993-1.
Materials used the construction of components that:

- contact the heated humidified gas pathway have been classified as permanent "external communicating devices" (with tissue/bone/dentin)
- contact the patient during the therapy have been classified as permanent "skin contact"

As relevant and to support the biocompatibility evaluation of each mask component, following biological effects (selected in accordance with FDA guidance #G95-1) were assessed:

- Genotoxicity (ISO 10993-3)
- Cytotoxicity (ISO 10993-5)
- Implantation (ISO 10993-6)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)

Mechanical integrity and performance of the new device was tested to simulated normal use and reasonable abuse scenarios. The device was also tested to demonstrate that it can withstand the effects of storage temperature, humidity and transportation shock & vibration.

Validation of cleaning and reuse was completed to establish that the device can be reused by a single patient (at home), or by several patients in the hospital/institutional environment.
Following validated disinfection protocols and after the number of cycles indicated in the published data for the AirSoft F15 mask, it was confirmed that the device continued to function as intended. The device was shown to be substantial equivalent to the predicate devices.

Clinical Data

Use of Full Face masks with CPAP or Bilevel therapy equipment is proven technology and is well accepted by the medical community. So was the case for the predicate devices, bench testing was sufficient to demonstrate substantial equivalence to the predicate devices.

Substantial Equivalence Conclusion

The new AirSoft F15 Mask System is substantially equivalent to the nominated predicate devices:

- it has the same intended use;
- it has similar technological and performance characteristics to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 9, 2014

ResMed Ltd.
c/o Jim Cassi
Vice President-Quality Assurance Americas
ResMed Corp.
9001 Spectrum Center Boulevard
San Diego CA 92123

Re: K132901
Trade/Device Name: AirSoft F15
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: June 4th, 2014
Received: June 4th, 2014

Dear Mr. Cassi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): **K132901**
Device Name: **AirSoft F15**
Indication for Use

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- to be used by patients (weighing >66 lb (30 kg)) for whom positive airway pressure therapy has been prescribed
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Prescription Use ____X_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

FDA Anya C. Harry -S
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